DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1313]

Guidance for Industry on How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final guidance for industry (#86) entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' to the Center for Veterinary Medicine (CVM). This final guidance provides guidelines to new animal drug sponsors (sponsors) on how to submit a notice of final disposition of animals not intended for immediate slaughter (NFDA) as an e-mail attachment by Internet. This electronic submission is part of CVM's ongoing initiative to provide a method for paperless submissions. This final guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments on the final guidance at any time.

ADDRESSES: Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the final guidance and the docket number found in brackets in the heading of this document.

Copies of the final guidance document entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/. Persons without Internet access may submit written requests for single copies of the final guidance to the Communications Staff

(HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2000 (65 FR 40104), FDA published the notice of availability of the draft guidance entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' (hereinafter referred to as the June 2000 notice). Interested persons were given until August 28, 2000, to submit comments. FDA received no comments.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; Electronic Signatures final regulation. This regulation (21 CFR part 11) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This rule also established docket number 92S–0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. The docket is accessible on the Internet at http://www.fda.gov/ohrms/dockets/dockets/92s0251.htm. CVM will identify in this public docket the types of documents that may be submitted in electronic form as those documents are identified in final guidance or regulations.

The electronic submission of NFDA's is part of CVM's ongoing initiative to provide a method for paperless submissions. This initiative reflects the principles behind the GPEA.

The GPEA of 1998 (Public Law 105–277) requires Federal agencies, by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or disclosure of

information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.

Before submitting NFDA's by e-mail, sponsors should first register and follow the instructions in final guidance for industry (#108) entitled ''How to Use E–Mail to Submit Information to the Center for Veterinary Medicine.'' This final guidance is also available at http://www.fda.gov/cvm.

CVM monitors the final disposition of food animals treated with investigational new animal drugs in situations where the treated animals do not enter the human food chain immediately at the completion of the investigational study. Monitoring of the final disposition of such food animals is consistent with CVM's responsibility to protect the public health under the Federal Food, Drug, and Cosmetic Act. In addition, acceptable standards of study conduct such as those set out in 21 CFR 514.117 include sponsors accounting for the disposition of all animals treated with investigational new animal drugs. Furthermore, CVM requests this information because some animals are held for 30 days after the investigational drug withdrawal period ends, and CVM does not request a notice of intent to slaughter for human food purposes for these animals. Animals held for this period may still be sent for slaughter, however. CVM issues a slaughter authorization letter to sponsors that sets the terms under which animals treated with investigational new animal drugs may be slaughtered (21 CFR 511.1(b)(5)). Also in this letter, CVM requests that sponsors submit NFDA's for animals that are treated with investigational new animal drugs and are not intended for immediate slaughter. NFDA's have historically been submitted to CVM on paper. This final guidance will give sponsors the option to submit an NFDA as an e-mail attachment to CVM via the Internet.

II. Significance of Guidance

This Level 1 final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The final guidance represents the agency's current thinking about using e-mail to submit an NFDA. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative

approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

In the June 2000 notice, FDA published a notice of the proposed collection of information related to the guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance document. No comments were received on the estimated annual reporting burden. The annual reporting burden estimate of 262 hours therefore remains unchanged. In the **Federal Register** of September 21, 2000 (65 FR 57193), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The information collection provisions related to this final guidance have been approved under OMB control number 0910–0453. This approval expires November 30, 2003.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this final guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (address above) written comments on this final guidance at any time. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket

number found in brackets in the heading of this document. A copy of the final guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 2001

Ann M. Witt,
Acting Associate Commissioner for Policy.

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